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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/486,070	06/07/95	STAVRIANPOULOS	J ENZ-7(F) (C3)

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HM31/1208

EXAMINER
MARSCHER, A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/08/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

08/486,070

Applicant(s)

Stavrianopoulos et al.

Examiner

Ardin H. Marschel

Group Art Unit

1634



☒ Responsive to communication(s) filed on 7/24/98, 8/17/98, and 9/21/98

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 48-100 and 102-182 is/are pending in the application.

~~Of the above, claim(s) 1-47 and 101 have been canceled. is/are withdrawn from consideration.~~

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 48-100 and 102-182 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants' arguments; filed 7/24/98, 8/17/98, and 9/21/98, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 60, 63, 77-99, 114, 118, 133, 136, 141, 144-161, 164, and 180-182 are rejected, as discussed below, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the disclosure as filed has failed to reveal the limitation of instant claims 60 and 114 directed to the support and system being composed of different materials. This limitation is therefore NEW MATTER. Consideration of the arguments and Declaration of Dr. Dean Engelhardt reveals that many alternatives were disclosed as filed directed to both porous and non-porous substrates or supports but that the citations pointed to lack any characterization wherein broadly different materials as given now in claims 60 and 114 are disclosed. This rejection is reiterated from the previous office action, mailed 1/21/98.

Claims 63, 86, 118, 146, 152, 164, and 180-182 have been amended to cite "a combination of any of the foregoing" or "combinations thereof" which are directed to DNA etc. This is NEW MATTER as written basis as filed for such combination practice has neither been pointed to by applicants nor been found by consideration of the instant disclosure as filed. This rejection is necessitated by amendment.

Claims 77-85, 87-99, 133, 136, and 141 contain NEW MATTER because the oligonucleotide or polynucleotide is cited as fixed or immobilized to the system rather than being limited to being fixed or immobilized to the solid support within such a system. Consideration of the disclosure as filed has not revealed fixing or immobilizing to a system as now cited in claims 77 etc. Applicants argue that original claims 20 and 23 give written support to said system immobilization of oligonucleotides etc. In response the written basis in these claims clearly contain "means" within devices or apparati thus not supporting the generic "system" limitation that has been noted above as NEW MATTER. This rejection is therefore maintained and reiterated from the previous office action, mailed 1/21/98, and necessitated by amendment due to newly added claims that contain the NEW MATTER either directly or via dependence from other claims.

Claims 144-161 and 180-182 contain NEW MATTER directed to enhancement of fixtation or immobilization with several treatments cited which have not been found as to written basis as

filed either. For example, the written basis for "a dispersive compound" of claim 148 has not been found as filed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 48-50, 53-56, 59, 61, 63-81, 84, 86-100, 102-104, 107-109, 113, and 115-132, 135-143, 152, 155, 156, 158, and 160-182 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kourilsky et al. (UK 2,019,408).

This rejection is reiterated and maintained from the previous office action, mailed 1/21/98, and necessitated by amendment regarding newly added claims. Applicants argue that ultracentrifugation is not immobilization or fixation. In response it is noted that resuspension as a distinct act is required in order to resuspend the pellet from said

ultracentrifugation. Such a required resuspension clearly supports the immobilized character of said pellet and supports this rejection. Applicants also argue that the signal of the reference is prevented from the pelleted product. This is non-persuasive because the instant claims do not contain any limitation that requires that the signal be generated while the nucleic acids are yet fixed or immobilized. That is, they can be resuspended as in the reference and capable of generating a soluble signal as this is not negated by any instant claim wording.

Applicants argue the below art rejections in that the practice of in-situ hybridization is a very specialized type of methodology and different from the soluble signal generation practice as instantly claimed. In response applicants are reminded that compositions, apparatus, and systems are claimed and not methods. Therefore, if a reference meets the composition, apparatus, or system limitations, it anticipates the instant invention even if a number of uses can be practiced for the claimed invention. In other words patentable weight is not given to use limitations if they do not limit the actual composition etc. limitations.

Claims 48-54, 56, 59, 61-79, 84-100, 102-108, 113, 115-134, 138-143, 152-158, and 162-182 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Stuart et al.

Applicants argue that Stuart et al. is concerned with in

situ hybridization and not applicable. This is non-persuasive as already discussed above. Applicants then argue that the instant invention requires chemically labeled nucleic acid for one of the strands. This is also non-persuasive because there is therein no limitation regarding whether a label may or may not also interact with the second strand in a hybrid formed during a hybridization assay. This rejection is reiterated and necessitated by amendment due to the newly added claims.

Claims 48-54, 56, 59, 61-79, 84-100, 102-108, 113, 115-134, 138-143, 152-158, and 162-182 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated either by Langer-Safer et al. or Manuelidis et al.

The listed claims are anticipated either by Langer-Safer et al. or Manuelidis et al. in the same manner as the above rejection based on Stuart et al. because both references also discussed the performance of in situ hybridization of chromosome spreads on microscope slides etc. as summarized above. This rejection is reiterated and necessitated by amendment due to the newly added claims.

Claims 48-100 and 102-182 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ward et al.

Ward et al. disclose via the "GENERAL PROTOCOL" and with connected discussion elsewhere at the bottom of columns 19 and 20 in situ hybridization where immobilized double-stranded nucleic acid is shown visualized with a biotinylated probe bound to

avidin-peroxidase. This reads on the listed claims as the peroxidase is capable of generating a soluble signal as discussed above and therefore still reads on the instant invention even though Ward et al. discloses insoluble signal generation. This rejection is reiterated and necessitated by amendment due to the newly added claims.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 100, 102-108, 110-132, 134, 139, and 142-182 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 4,994,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain common embodiments regarding devices. It is noted that a terminal disclaimer was filed in the immediate parent to the instant application, however, when a new



application serial number is utilized due to the instant application being a continuation of said parent a new terminal disclaimer must be filed. It is noted that applicants' arguments have been persuasive for the instant composition claims but that claim 17 of the patent is a device which falls into the same restriction group as the above rejected instant claims.

The disclosure is objected to because of the following informalities:

The specification has been amended at pages 18, 24, and 25 to indicate that the generic name for TRITON X-100 is "octoxymol" which conflicts with the Merck Index spelling of "octoxynol".

Appropriate correction is required.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law

103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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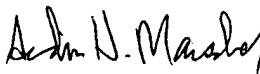
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

December 7, 1998

  
**ARDIN H. MARSCHEL**  
**PRIMARY EXAMINER**